

## **PART III: PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE PATIENT MEDICATION INFORMATION**

**PrLIXIANA®**

**Edoxaban Tablets (as edoxaban tosylate monohydrate)**

Read this carefully before you start taking **LIXIANA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LIXIANA**.

#### **What is LIXIANA used for?**

- To lower the risk of blood clots:
  - in the brain (stroke) and
  - in other blood vesselsin people who have atrial fibrillation (a type of irregular heartbeat).
- To treat and prevent blood clots in the veins of the legs (deep vein thrombosis) or lungs (pulmonary embolism).

It is not known if LIXIANA is safe and effective in children.

#### **How does LIXIANA work?**

LIXIANA helps to reduce the risk of the formation of blood clots. LIXIANA blocks a protein called factor Xa. Factor Xa is involved in the natural formation of blood clots.

#### **What are the ingredients in LIXIANA?**

Medicinal ingredients: edoxaban tosylate monohydrate

Non-medicinal ingredients: carnauba wax, crospovidone, hydroxypropyl cellulose, hypromellose, iron oxide red (30 mg tablets and 15 mg tablets), iron oxide yellow (60 mg tablets and 15 mg tablets), magnesium stearate, mannitol, polyethylene glycol 8000, pregelatinized starch, talc, titanium dioxide.

#### **LIXIANA comes in the following dosage forms:**

Tablets: 15 mg, 30 mg and 60 mg

#### **Do not use LIXIANA if:**

- You are at risk of serious bleeding. This may be because you:
  - had recent bleeding in the brain.
  - have active ulcers that are bleeding or were recently bleeding.
- You have liver and blood-clotting problems.
- You are pregnant or breast-feeding.

- You are already being treated with a drug that stops your blood from clotting. Examples include: warfarin, dabigatran, or apixaban.
- You are allergic to:
  - edoxaban (active ingredient of LIXIANA) or
  - any of the other ingredients in LIXIANA.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LIXIANA. Talk about any health conditions or problems you may have, including if you:**

- are at risk of bleeding- This may be because you have or have had:
  - bleeding disorders.
  - an ulcer in your stomach or bowel.
  - bleeding in your brain, stomach or bowel.
  - very high blood pressure, not controlled by medical treatment.
  - an operation on your brain, spinal column or eye.
- take any drug that stops your blood from clotting.
- take aspirin, naproxen or ibuprofen (non-steroidal anti-inflammatory medications) on a regular basis.
- have liver or kidney problems.
- have a blockage in an artery in your lungs.
- have a catheter that stays in your bladder.
- have a body weight below 132 lbs (60 kg).
- have a mechanical heart valve.
- have a heart problem as a result of rheumatic fever.
- had a recent injection into your spine such as an epidural.
- have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk in blood clots).
- plan to become pregnant or if you are pregnant. It is not known if LIXIANA will harm your unborn baby. Tell your doctor right away if you become pregnant during treatment with LIXIANA.
- plan to breastfeed or if you are breastfeeding. It is not known if LIXIANA passes into your breast milk. You and your doctor should decide if you will take LIXIANA or breastfeed. You should not do both.
- plan to have any surgery or a dental procedure. Tell all of your healthcare professionals and dentists that you are taking LIXIANA. They should talk to the doctor who prescribed LIXIANA for you. This should be done before you have any surgery or dental procedure. You may need to stop and restart your treatment with LIXIANA.

## **Other warnings you should know about:**

### **Risk of bleeding**

- Taking LIXIANA may result in serious bleeding. You may bleed from your organs and you may die.
- Do not stop taking LIXIANA without first talking to your doctor. This is important because blood clots may occur in the brain or in other blood vessels. This can cause death or severe disability.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### **The following may interact with LIXIANA:**

Taking LIXIANA with some other drugs may increase the risk of bleeding. Some of these drugs are:

- Cyclosporine, dronedarone, erythromycin, ketoconazole, quinidine, verapamil.
- Anticoagulants (medications to prevent blood clots).
- Aspirin and other nonsteroidal anti-inflammatory drugs such as naproxen.
- Drugs that block the action of platelets, such as clopidogrel.
- Antidepressants called selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine, or serotonin norepinephrine reuptake inhibitors (SNRIs), such as duloxetine.

### **How to take LIXIANA:**

- You can take LIXIANA with or without food.
- Take LIXIANA exactly as prescribed by your doctor. Make sure to refill your prescription before you run out.
- **Do not stop taking LIXIANA without first talking with your doctor. Stopping LIXIANA may increase your risk of blood clots.**
- If you plan to have surgery, or a medical or a dental procedure, tell your doctor and dentist that you are taking LIXIANA. You may have to stop taking LIXIANA for a short time.
- Call your doctor right away if you fall or injure yourself, especially if you hit your head. Your doctor may need to examine you.

### **Usual dose:**

- *To reduce the risk of blood clots in your brain (stroke) and other blood vessels*
  - 60 mg once a day
- *To treat and prevent blood clots in the veins of your legs or lungs*
  - 60 mg once a day.
  - You will receive LIXIANA after you have been given an injectable anticoagulant over 5-10 days.

- *Dose reductions*
  - The dose of LIXIANA is 30 mg once a day if you have one or more of the following:
    - Severe or Moderate kidney problems
    - Low body weight of 60 kg (132 lbs) or less
    - You take P-gp inhibitors (type of medication) except for amiodarone and verapamil (types of P-gp inhibitor) while taking LIXIANA.

**Overdose:**

There are very few experiences of overdose with LIXIANA. Overdose with LIXIANA may lead to bleeding.

If you think you have taken too much LIXIANA, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

- If you miss a dose of LIXIANA, take it as soon as you remember on the same day.
- Take your next dose at your usual time the next day.
- Do not take more than one dose of LIXIANA at the same time to make up for a missed dose.

**What are possible side effects from using LIXIANA?**

These are not all the possible side effects you may feel when taking LIXIANA. If you experience any side effects not listed here, contact your healthcare professional.

LIXIANA affects blood clotting. Most side effects are related to bleeding. LIXIANA can cause bleeding that is serious and may lead to death.

Patients treated with LIXIANA may experience the following side effects:

- Rash or itchy skin

Serious side effects and what to do about them			
Symptom / Effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
<b>Anemia:</b> fatigue, loss of energy, weakness, shortness of breath		✓	
Bleeding from nose	✓		
<b>Bleeding in the stomach or bowel:</b> dark stool (like tar), bright red blood in your toilet or on toilet tissue, vomiting blood		✓	
Bleeding from mouth or gums	✓		
Bruising and swelling		✓	
<b>Blood in urine:</b> pink or red urine		✓	
<b>Vaginal bleeding:</b> Increase in or more frequent menstrual bleeding, unexpected vaginal bleeding		✓	
<b>UN-COMMON</b>			
<b>Bleeding into the brain:</b> sudden, severe and unusual headache			✓
Bleeding in eyes		✓	
Coughing blood or blood stained sputum		✓	
Bleeding from the surgical wound, an injury or other medical procedure		✓	
<b>Allergic reactions:</b> rash, itching, hives, trouble swallowing or breathing (angioedema), throat tightening or constriction, swelling of the face, lips or tongue, sudden low blood pressure.			✓
<b>Stevens-Johnson syndrome (SJS)</b> (severe skin reactions): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands.			✓
<b>RARE</b>			
<b>Bleeding into muscles:</b> sudden pain or swelling in your muscles		✓	
<b>Bleeding into a joint:</b> stiff, sore, hot or painful joint		✓	
<b>UNKNOWN</b>			
Abdominal pain	✓		
Dizziness	✓		
Headache	✓		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

- Store LIXIANA at room temperature between 15°C to 30°C.
- Keep in a safe place out of the reach and sight of children.

### **If you want more information about LIXIANA:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](http://hc-sc.gc.ca/index-eng.php) (<http://hc-sc.gc.ca/index-eng.php>) or by calling the manufacturer, Servier Canada Inc. at: 1-800-363-6093.

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